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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,030	12/11/2003	Glade H. Howell	P-3855C1C1C1	8757
26253 7590 06/04/2009 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company 1 Becton Drive MC 110 Franklin Lakes, NJ 07417-1880				
EXAMINER VU, QUYNH-NHU HOANG				
ART UNIT 3763		PAPER NUMBER		
MAIL DATE 06/04/2009		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/734,030

**Applicant(s)**

HOWELL, GLADE H.

**Examiner**

QUYNH-NHU H. VU

**Art Unit**

3763

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 April 2009.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-4, 6-9 and 13-23 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-4, 6-9, 13-23 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

Amendment filed on 4/6/09 has been entered.

Claims 1-4, 6-9, 13-23 are present for examination.

Claims 5, 10-12 are cancelled.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "...wherein the biasing element is disposed in the housing about the septum and in contact with the outside longitudinal surface of the septum" is vague. Does Applicant mean that: the biasing element 56 is disposed in the housing and in contact with the outside longitudinal surface of septum at groove portion 54?

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brimhall et al. (US 5,810,780) in view of Poli (US 5,396,925).

Brimhall discloses a vascular device comprising: a housing (including 25 and 41); a septum 30 having an opening/slit wherein a needle 40 may pass into the septum; the septum disposed in the housing.

Brimhall does not disclose a biasing element operably engaged to the septum urging the opening to a closed condition.

As know that, a septum of claimed invention is considered as a valve for sealing blood and preventing the leakage of blood.

Similarly, Poli discloses a flush valve that normally limits a flow of fluid or blood through the valve. The device of Poli in Fig. 7A is similarly to the septum in Fig. 2 of claimed invention. For example: Poli discloses that a biasing element 72 engaged to the septum urging the septum to a closed condition; a slit 36 (Fig. 7B). Poli does not clearly mention that the biasing element 72 formed of C-shaped. However, it would have been an obvious matter of design choice to provide the biasing element with C-shaped, since applicant has not disclosed that C-shaped solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the biasing element of Poli.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Brimhall with a biasing element, as taught by Poli, in order to limit a flow of fluid through the valve.

Claims 8-9, 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brimhall et al. (US 5,810,780) in view of Crawford et al. (US 5,558,651) and Poli (US 5,396,925).

As best as understood, Brimhall discloses a vascular access device comprising: a catheter 20, a housing (including element 24 and 41) in fluid connection with the catheter; a septum 30 disposed within the housing and having a length disposed in the housing; a needle 40 slidably disposed with respect to the catheter, the needle having a proximal end and a distal end with an opening at the proximal end, wherein the needle defines a notch 42 therein adjacent to the distal end, and wherein a notch distance is defined as the distance between a proximal end of the notch and a distal end of the opening in the distal end of the needle.

Brimhall does not disclose the limitations that the septum having a biasing element disposed in the housing as described in claim 1. Brimhall does not disclose that the length of the septum is greater than the notch distance such that leakage of bodily fluid emanating from the distal end of the needle.

Crawford discloses a device comprising: a needle 15 with an opening 15; wherein the needle defines a notch 28 therein adjacent to the distal end 17, and wherein a notch distance is defined as the distance between a proximal end of the notch and a distal end of the opening in the distal end of the needle; a catheter 13; a septum (including 11 and 30). Fig. 1 of Crawford clearly shows that the septum having a length greater than the notch distance.

As known that, a septum of claimed invention is considered as a valve for sealing blood and preventing the leakage of blood.

Similarly, Poli discloses a flush valve that normally limits a flow of fluid or blood through the valve. The device of Poli in Fig. 7A is similarly to the septum in Fig. 2 of claimed invention. For example: Poli further discloses in Fig. 7B that the septum and urging the septum to a closed condition wherein the biasing element 72 is in contact with the outside longitudinal surface of the septum; wherein the biasing element is in a single fixed location with respect to the housing and continuously exert a biasing force on the septum, wherein said septum further comprises an annular groove 28 disposed in the outer surface of the septum and wherein the biasing element is placed in contact with the annular groove.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Brimhall with a notch, as taught by Crawford, so that the alignment of the septum/pawl with the notch and the blood can be leaked within the septum. Furthermore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Brimhall with a biasing element, as taught by Poli, in order to limit a flow of fluid through the valve.

As known that, since the septum of Brimhall disposed in the housing, while the biasing element of Poli attached to the septum as described above. Therefore, one skill in the art would recognize that the biasing element must be located in the housing also.

Claims 13-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brimhall et al. (US 5,810,780) in view of Crawford et al. (US 5,558,651) and Poli (US 5,396,925) and further in view of Bimba (US 4,600,221) or Gregory (US 3,967,645).

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Brimhall in view of Crawford and Poli discloses the invention substantially as claimed. Brimhall in view of Crawford and Poli do not clearly mention that the biasing element 72 formed of C-shaped metal clip.

It would have been an obvious matter of design choice to provide the biasing element with C-shaped, since applicant has not disclosed that C-shaped solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the biasing element of Poli.

As noted that the biasing element 72 of Poli made of plastic and resilient. The biasing element is same as clip function. It is well-known in the art to provide the biasing element/clip made of spring metal. For example: Bimba provides the metal clip 50 or Gregory discloses a C-shaped metal clip.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Brimhall in view of Crawford and Poli with a metal clip instead of plastic clip, as taught by Bimba or Gregory, in order to increase the strength and compress onto portion of valve device in certain force to keep the valve in close position.

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the metal clip, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-4, 6-9, 13-23 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date

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of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763